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TREATMENT BURDEN ON TYPE 2 DIABETICS TAKING MEDICATION ORALLY, INJECTABLY AND BOTH THE MODES

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ABSTRACT

Type 2 diabetes effects functioning and well being, thus impacting quality of life. The study assessed, analysed, captured the Treatment Burden among Type 2 Diabetics taking medication orally, injectably and through both the modes; and explored, assessed and compared the demographic and lifestyle factors. 400 diabetics with males and females ratio of 50:50 from OPD Endocrinology of Post Graduate Institute of Medical Research, Chandigarh, India were assessed. A self designed and diabetes specific validated questionnaire on Treatment Burden were used. Study revealed that respondents taking medication injectably had higher treatment burden as it increased anxiousness of pain. Females taking medication orally and through both the modes suffered higher burden as compared to males. Education showed direct correlation to treatment burden as burden increased with education among respondents taking medication orally and injectably. Treatment burden was highest among respondents of 30-59 years taking medication orally and injectably. Newly detected diabetics taking medication orally felt maximum burden. Irrespective of mode of medication, respondents sleeping less than 7 hours and watching television for more than 2 hours per day had higher treatment burden. Quality of life influenced self care activities. A multidisciplinary approach in healthcare is essential for improvement their quality of life.

KEY WORDS

Type 2 Diabetes, Quality of Life, Treatment Burden, Medication, Lifestyle and Demography.

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INTRODUCTION[1]

Diabetes mellitus, a metabolic disease defined by abnormalities of fasting or postprandial glucose requires lifelong treatment which includes medication to control blood glucose levels effecting functioning and well being of diabetics, thus

impacting the quality of life. According to the American Diabetes Association along with the consultation of W.H.O., the term Diabetes Mellitus has been described as a metabolic disorder of multiple etiology. It is characterized by chronic hyperglycemia with disturbance of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. The effects of diabetes mellitus include long-term damage, dysfunction and failure of various organs. Diabetes mellitus may present characteristic symptoms such as thirst, polyuria, blurring of vision, and weight loss. In its most severe forms, ketoacidosis or a non-ketotic hyperosmolar state may develop and lead to stupor, coma and, in absence of effective treatment, death[1]. India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed the Diabetes Capital of The World[2]. Quality of Life is a holistic concept which addresses many aspects of health. It has been defined by World Health Organization (W.H.O.) as, *"an individual's perception of their position on lifein the context of culture and value system in which they live and relation to their goals, expectations, standard and concerns"*[3].Quality of life measures the extent to which people's happiness requirements is met, that is, those requirements which are necessary (all though not sufficient) condition of anyone's happiness- those „without which no member of human race can be happy"[4]. Diabetes is one of the most debilitating common illnesses which requires lifelong management, often including medication to control blood glucose levels the treatment can be varied in terms of more of administration (oral, syringe, pen, pump) as well as type of anti- diabetic agents (e.g. oral hypoglycemic agents or insulin)[5]. Quality of life influences the patients‟ self care activities, which may constantly impact their diabetes control and management[6]. It has been seen that of the weighted prevalence of diabetes (both known and newly diagnosed) was 10.4% in Tamil Nadu, 8.4% in Maharashtra, 5.3% in Jharkhand, and 13.6% in Chandigarh. The prevalence of prediabetes (impaired fasting glucose and/or impaired glucose tolerance) were 8.3%, 12.8%, 8.1% and 14.6% respectively, wherein Chandigarh topped the list[7]. In a study done by United Kingdom Prospective Diabetes Study, it was noted that many patients with Type 2 Diabetes facing the possibility of insulin being added to their treatment were concerned and worried about its effect on Quality of Life. They were anxious about the pains of injections and concerned about proper technique. The findings suggested that the injectable therapy improved the Quality of Life relatively higher than the oral therapy even when similar levels of glycemic control were achieved[8]. In the developing countries, majority of the people with diabetes are in the 45 to 64 year age range[9,10]. Several predisposing risk factors simultaneously affect the development of diabetes- i.e obesity, physical inactivity, gender, sex and advancing age. To some extent, these predisposing risk factors exacerbate the major risk factors dyslipidemia, hypertension and glucose intolerance[11]. In a study by Nanne Kleefstra et al, investigation of the relationship between health-related quality of life (HRQoL) and mortality in type 2 diabetes was carried out. This study emphasized that in patients with type 2 Diabetes, it was important to look beyond clinical parameters[12]. In a study done by Harsimran Singh and Clare Bradley in 2006, the need to assess Quality of Life, it was seen that treatment of diabetes may damage the quality of life of patients even if it improved health[13]. In a study done to access the quality of life of type 2 diabetic patients by Redekop et al it was found that older age female, female, insulin therapy, presence of complications and obesity were associated with a lower quality of life[14]. Patients with diabetes perceive significant differences in the quality of life effects of treatment related to their conditions. It was found that the patients perceived comprehensive diabetes care as having significant negative effects on quality of life, and these effects were equivalent to life with several intermediate complications. This quality of burden appeared to have arisen from the prospect of multiple daily insulin injections rather than the prospect of multiple oral agents. This is implied by the facts that the treatment states with the lowest ratings include the daily injections of insulin and the utilities for comprehensive diabetes care and comprehensive care with polypill were not

significantly different[15]. In a study done by UKPDS, it was noted that many patients with Type 2 Diabetes facing the possibility of insulin being added to their treatment were concerned and worried about its effect on Quality of Life they were anxious about the pains of injections and concerned about proper technique. The findings suggested that the injectable therapy improved the Quality of Life relatively higher than the oral therapy even when similar levels of glycemic control were achieved[16].On the other hand in a study done by Redekop et al (2002) on a sample size of 1,348 with type 2 diabetes in the Netherlands, it was observed that patients treated with insulin reported a lower quality of life than patients using oral therapy[14]. In a multivariate analysis adjusting for age, smoking, exercise levels, dietary factors and other covariates, each 2-hours/day increment in TV watching was associated with a 23% increase in obesity and a 14% increase in risk of diabetes; whereas each 2-hours/day increment in sitting at work was associated with a 5% increase in obesity and a 7% increase in diabetes[17]. In contrast, standing or walking around at home 2-hours/day was associated with a 9% reduction in obesity and a 12% reduction in diabetes[18].According to the World Health Organization, it is estimated that 1.9 million deaths worldwide are attributable to physical inactivity each year. Watching television/DVDs/videos and computer use is associated with the development of obesity and poor dietary habits. Therefore, guidelines have been published to limit sedentary activities to less than 2 hours per day[17]. In a study done by Francesco et al which included 10 studies (1,07,756 males and females participants and 3,586 incident cases of type 2 diabetes) through which association between measures of quantity of habitual sleep and the incidence of Type 2 Diabetes was provided. An unambiguous and consistent pattern of increased risk of developing Type 2 Diabetes was seen at either end of the distribution of sleep duration, and with qualitative disturbances of sleep. Risk of 28% was reported in people who slept for less than 5-6 hours/ sleep and 84% in those with difficulties in maintaining their sleep[19].

To fully understand the patients perceptions of the impact of treatment on functioning and well-being must be accurately assessed. Thus, keeping this view in mind, the study was conducted assess, analyse, capture the Treatment Burden on Quality of Life among Type 2 Diabetic patients taking medication orally, injectably and through both the modes, and to explore, assess and compare the demographic and lifestyle factors

MATERIALS AND METHODS

The current study was conducted on a sample of 400 type 2 diabetic patients which constituted of 200 males and 200 female patients. The study was conducted on consecutive patients presenting with type 2 diabetes, visiting the O.P.D., Endocrinology Department, of Post Graduate Institute of Medical Research, Sector 12, Chandigarh, India.

For studying all the parameters and to get maximum information from the patients, both open ended and closed ended questions were included. The questions were kept simple, unambiguous, and free from any kind of religious or cultural bias. The questions were kept suitable to Indian context. They were framed in such a manner such that the patients could answer them with free mind. Some questions were put to them in different manners so that accurate information could be obtained from them in a polite manner. A pilot study was carried out to test the practicality and feasibility of the questionnaire. On this basis, appropriate changes were made in the questions to get clarity of response. After refining the questionnaire, structured interview was carried out with each of the study subjects.

The questionnaires comprised of a self designed questionnaire for filling mode of medication, demographic and lifestyle factors included gender, age, educational qualifications, occupation, duration of diabetes, sleep hours and television viewing, and a Diabetes Specific five point response with 6 item (30 points- higher the value, lower was the Treatment Burden) validated questionnaire on Treatment Burden was used for the study.

The demographic information of every sample was written down carefully. The name, age, sex, address, rural/urban status and the contact numbers of every sample were noted. Their educational qualification

and occupation was also taken down. The samples were asked as to at what age did diabetes set in them and that for how long had they been diabetic.

Information on lifestyle was assessed by knowing the patients‟ television viewing hours as well as sleep hours. To enquire about their sleep hours, they were asked simple questions like, "how many hours do you sleep in the whole day?" The question was also broken up as "how many hours do you sleep during the afternoon and at night?", so as to get the accurate figure of hours of sleep. Those samples reported with seven hours of sleep per day served as the reference group. Similarly, questions related to television viewing like, "how many hours of television do you watch in the whole day?"; "how many serials do you watch in the whole day?"; "do you watch news on television? For how long?", were asked. The guidelines for television viewing hours have been set as not more than 2 hours by the World Health Organization[17].

The questions related to Treatment Burden were Diabetes Specific five point response with 6 item (30 points- higher the value, lower was the Treatment Burden) from a validated questionnaire, Treatment Related Impact Measure- Diabetes (Figure No.1). It had five point response option ranging from not at all/never to extremely/almost always, always or extremely dissatisfied/inconvenient or extremely satisfied/convenient[6]. The questions in the questionnaires were asked one by one. They were asked in different manners, so as to make the patient understand the question properly with the aim of getting appropriate information from them.

The questions asked as per the questionnaire to the respondents were:

Statistical Analysis

The data taken from every patient was recorded on a pre designedperforma as well as on the validated questionnaires. Before entering the data on an excel spread sheet, the performa and the validated questionnaires were reviewed for any incomplete information. After filling the entries on the excel sheet, the data was checked again for any possible keyboard error.

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation and standard error). Means were compared using one-way ANOVA (analysis of variance) for more than two groups. For two groups t-test was applied. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using Chi square or Fisher‟s exact test whichever was applicable. All statistical tests were two-sided and performed at a significance level of α=.05.

RESULTS

Treatment Burden

In this parameter, higher the mean, lower was the treatment burden felt by samples. It was observed that the samples taking medication through both the modes felt minimum treatment burden, followed by those who took medication orally. The maximum burden was felt by samples who took insulin injections. A statistically significant difference was observed between oral with injectable and injectable with both modes of medication (Table No.1).

In a study done by Harsimran Singh and Clare Bradley in 2006, the need to assess Quality of Life, it was seen that treatment of diabetes may damage the quality of life of patients even if it improved health[13]. Patients with diabetes perceive significant differences in the quality of life effects of treatment related to their conditions. It was found that the patients perceived comprehensive diabetes care as having significant negative effects on quality of life, and these effects were equivalent to life with several intermediate complications. This quality of burden appeared to have arisen from the prospect of multiple daily insulin injections rather than the prospect of multiple oral agents. This is implied by the facts that the treatment states with the lowest ratings include the daily injections of insulin and the utilities for comprehensive diabetes care and comprehensive care with polypill were not significantly different[15]. In a study done by UKPDS, it was noted that many patients with Type 2 Diabetes facing the possibility of insulin being added to their treatment were concerned and worried about its

effect on Quality of Life they were anxious about the pains of injections and concerned about proper technique. The findings suggested that the injectable therapy improved the Quality of Life relatively higher than the oral therapy even when similar levels of glycemic control were achieved[16]. On the other hand in a study done by Redekop et al (2002) on a sample size of 1,348 with type 2 diabetes in the Netherlands, it was observed that patients treated with insulin reported a lower quality of life than patients using oral therapy[14].

Treatment Burden between Genders

It was observed that the males were more satisfied in the mode of medication through oral and both with the treatment as compared to females. The females were more satisfied than males where they took medication through injections and the difference was observed to be statistically insignificant in all the categories (Table No.2).

Treatment Burden and Age

As shown in Figure No.2, it was observed that in samples taking medication orally and through injections, the treatment burden was more in those between the age group of 30- 59 years. The burden was observed to be less in the non working age group samples which were below 29 years and above 60 years. In samples taking medication through both the modes, the treatment burden was observed to be approximately similar in all age groups and the difference was statistically insignificant in all the categories. However, in a study done to access the quality of life of type 2 diabetic patients by Redekop et al it was found that older age was associated with a lower quality of life[14]. Patients with diabetes perceive significant differences in the quality of life effects of treatment related to their conditions[15].

Treatment Burden and Educational Levels

In Figure No.3, it was evident that higher levels of treatment burden due to medication were felt higher among samples who were graduates and above graduates, taking medication orally and through injections. In those samples who were taking medication through both the modes, the treatment burden was almost equivalent in all education levels. The difference was observed to be statistically insignificant in all the categories.

Treatment Burden and Occupation

It was observed, as depicted in Figure No.4, that in samples taking medication orally, the treatment burden was minimum in those who were retired, housewives and businessmen. In samples taking medication through injections, the treatment burden was observed to be similar in all categories of occupation except in businessmen who were maximally burdened due to treatment. In samples taking medication through both modes, farmers and labourers and businessmen felt the least burden of the treatment though they were less in number. The difference was observed to be statistically significant in samples between labourers and farmers with businessmen consuming medication orally.

Treatment Burden and Duration of Diabetes

As Figure No.5 shows, maximum treatment burden was felt by newly detected diabetic samples taking medication orally. In the category taking medication through injections, maximum treatment burden was felt by those who had been diabetic for more than 5 years. The treatment burden of samples taking medication through both modes did not show much difference as respect to duration of diabetes. No statistical significant difference was observed on the basis of duration of diabetes.

Treatment Burden and Lifestyle

Irrespective of the mode of medication, as Figure No.6 (a) and Figure No.6 (b), respondents who slept less than 7 hours and watched television for more than 2 hours per day had a higher treatment burden. Amongst Sleep Hour parameter, the difference was observed to be statistically significant in patients between sleep of below 7 hours with 7 hours taking medication orally but insignificant in the other categories. In a multivariate analysis adjusting for age, smoking, exercise levels, dietary factors and other covariates, each 2-hours/day increment in TV watching was associated with a 23% increase in obesity and a 14% increase in risk of diabetes; whereas each 2-hours/day increment in sitting at work was associated with a 5% increase in obesity and a 7% increase in diabetes. In contrast, standing or walking around at home 2-hours/day was associated with a 9% reduction in obesity and a 12% reduction in diabetes[18]. An unambiguous and

consistent pattern of increased risk of developing Type 2 Diabetes was seen at either end of the distribution of sleep duration, and with qualitative disturbances of sleep. Risk of 28% was reported in people who slept for less than 5-6 ours/ sleep and 84% in those with difficulties in maintaining their sleep[19].

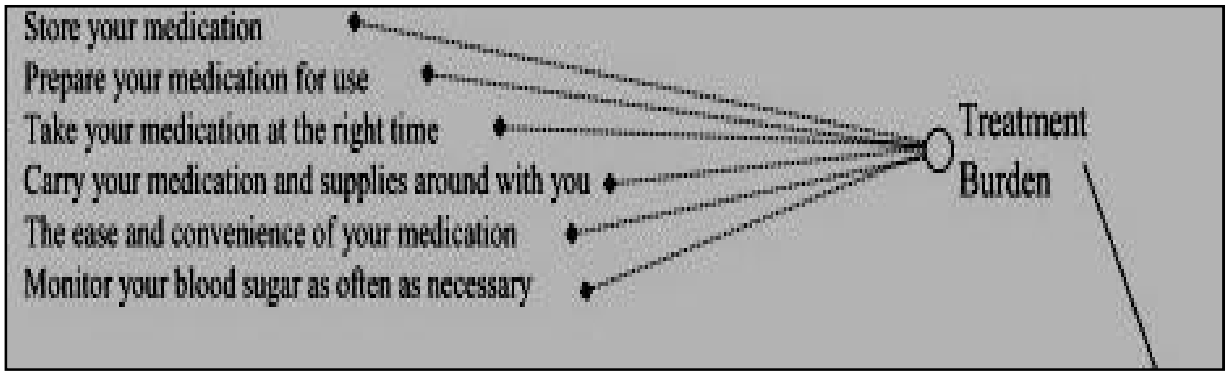
Table No.1: Treatment Burden

S.No	Parameter	Medication	Mean ± Standard Deviation	Significance	
1	Treatment burden (30 points questions)	Oral	27.30± 3.72	0.021*	---
		Injection	25.90 ±5.23		0.010*
		Both	27.56 ±3.61	---	
Total			27.03 ±4.16	---	---

Table No.2: Treatment Burden between Genders

S.No	Medication	Sex	Mean ± Standard Deviation	Significance
1	Oral	Males	27.79±3.55	0.084
		Females	26.84±3.84	
2	Injection	Males	25.46 ±5.34	0.374
		Females	26.40 ±5.13	
3	Both	Males	28.00 ±2.80	0.197
		Females	27.13 ±4.24	

Figure No.1: The questions related to Treatment Burden were Diabetes



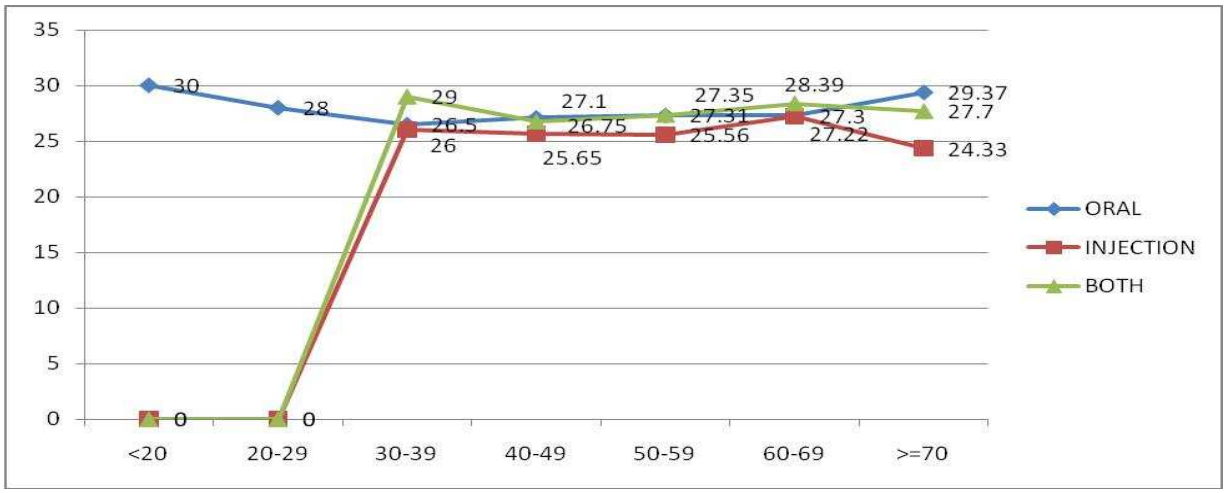


Figure No.2: Treatment Burden and Age

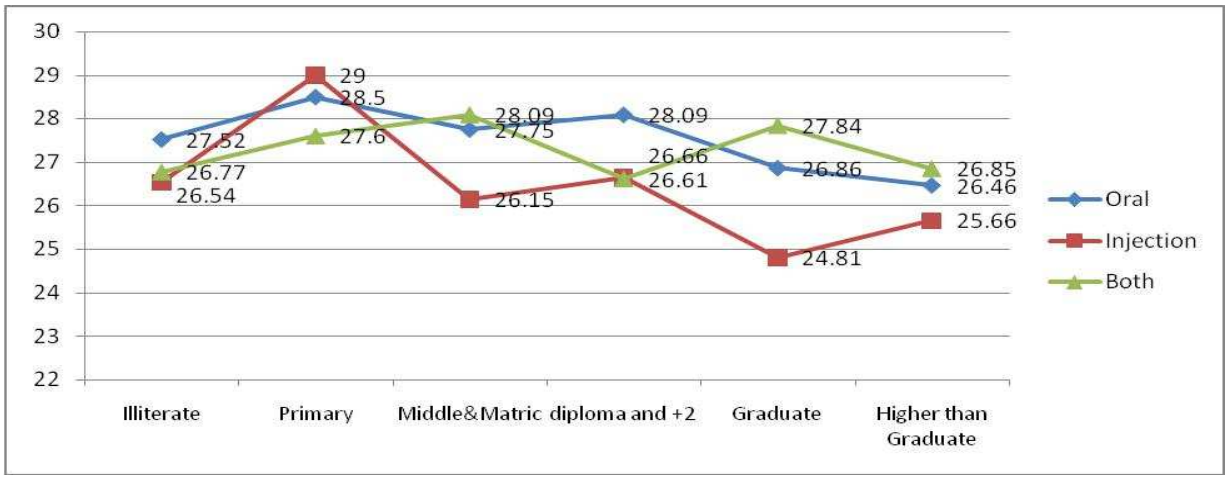


Figure No.3: Treatment Burden and Educational Levels

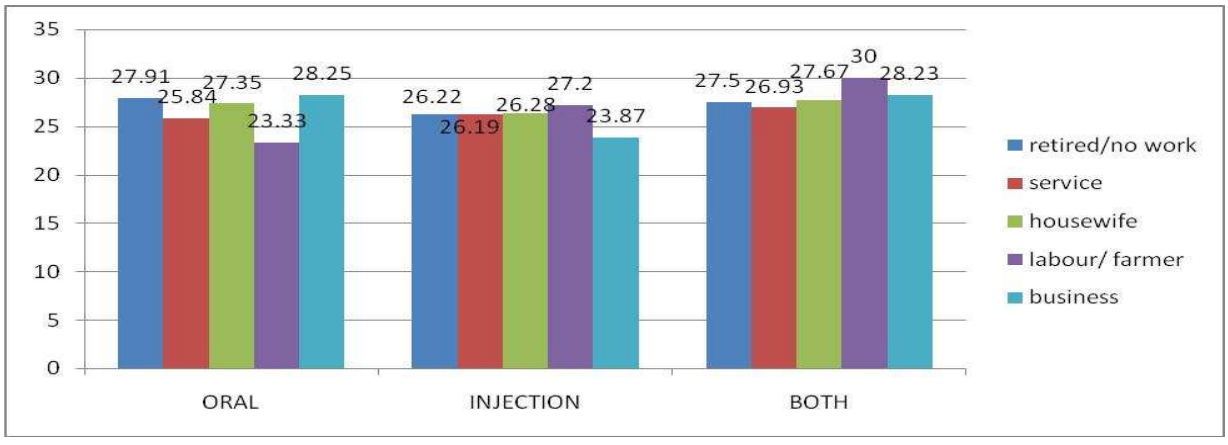


Figure No.4: Treatment Burden and Occupation

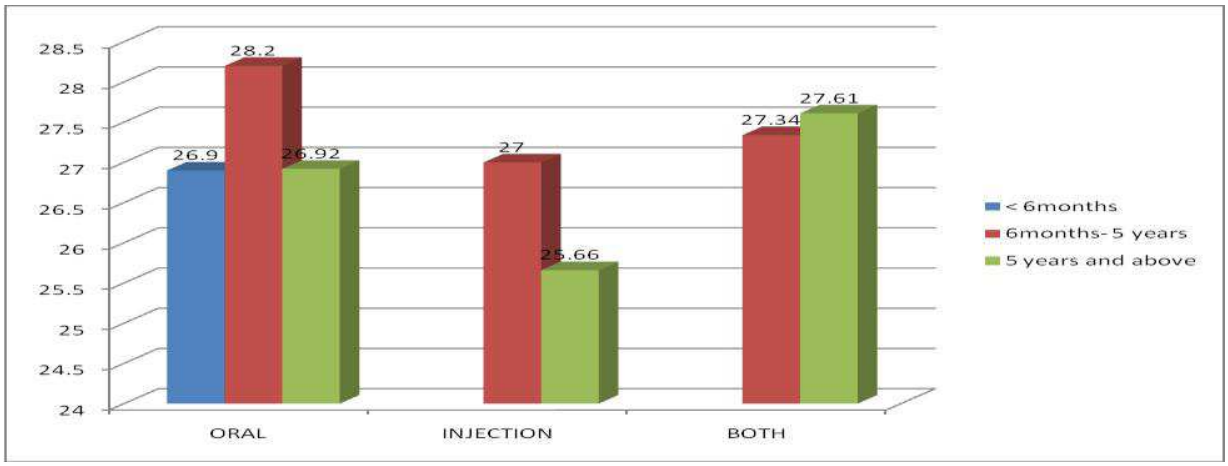


Figure No.5: Treatment Burden and Duration of Diabetes

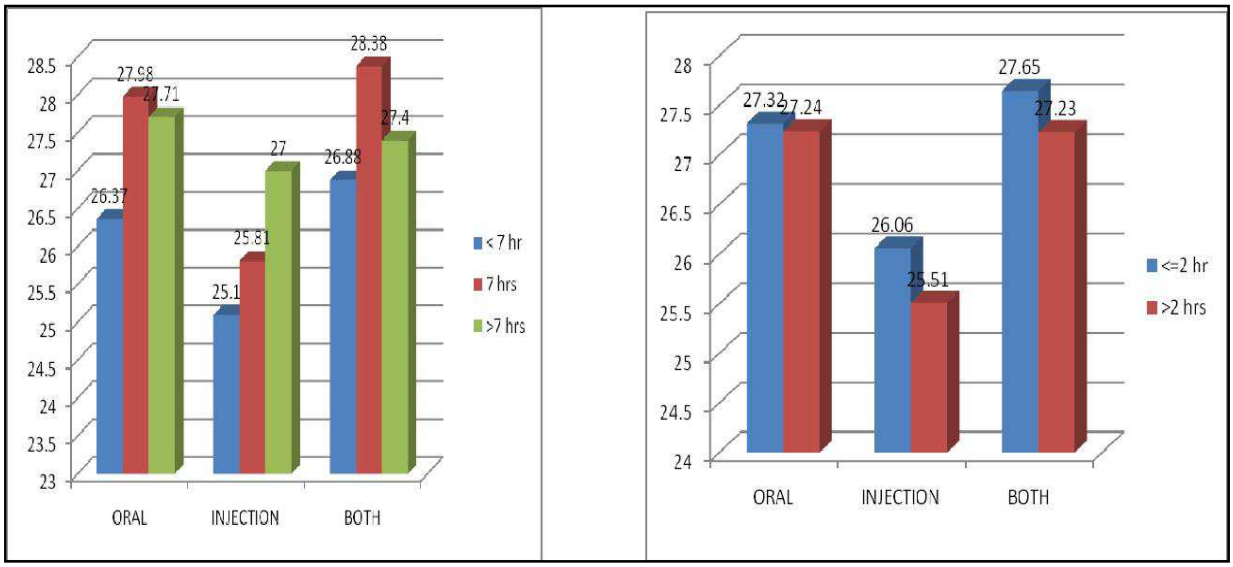


Figure No.6: Treatment Burden and Lifestyle

Figure No.6 (a): Treatment Burden and Sleep Hours

Figure No.6 (b): Treatment Burden and Television viewing

CONCLUSION

Diabetes is a debilitating common illness requiring lifelong management, which includes administration of medication orally or injectably or through both the modes to control blood glucose as well as administration of hypoglycemic agents or insulin anti- diabetic agents. The study reiterated the previous findings that the treatment burden was higher among diabetics taking medication through injections as they were anxious about the pains of injections and concerned about proper technique. It increased their concern and worries as they found it cumbersome. Females taking medication orally and through both the modes suffered higher burden as compared to males. Education was seen to have a direct correlation to treatment burden. Ageing depicted lowered level of quality of life. A multidisciplinary approach in healthcare where a cohesive environment of medical practitioners, qualified nutritionists, psychologists and paramedic staff is essential for a qualitative and comprehensive approach to enhance the quality of life of diabetics.

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